DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 20, 2015

LENSAR, Inc.
Dr. Mohinder Merchea
VP, Clinical & Regulatory Affairs
2800 Discovery Drive
Suite 100
Orlando, Florida 32826

Re: K143010
Trade/Device Name: Lensar Laser System - Fs 3d
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: OOE, HQC,
Dated: February 13, 2015
Received: February 18, 2015

Dear Dr. Merchea:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143010

Device Name
LENSAR Laser System - fs 3D (LLS-fs 3D)

Indications for Use *(Describe)*
The LENSAR Laser System - fs 3D (LLS-fs 3D) is intended for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, laser phacofragmentation, and the creation of full and partial thickness single-plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

This 510(k) summary is submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

LENSAR, Inc.
2800 Discovery Drive, Suite 100
Orlando, FL 32826

Phone: (888) 536-7271
Fax: (407) 386-7228

Contact Person(s): Mohinder Merchea
Date Prepared: October 6, 2014

II. DEVICE

Name of Device: LENSAR Laser System - fs 3D (LLS-fs 3D)
Common or Usual Name: LENSAR Laser System - fs 3D (LLS-fs 3D)
Classification Name(s): Ophthalmic Laser (21 CFR 886.4390),
Phacofragmentation System (21 CFR 886.4670)
Regulatory Class: II
Product Code(s): OOE; HQC

III. PREDICATE DEVICES

LENSAR Laser System – fs 3D (LLS-fs 3D), K123859
This predicate has not been subject to a design-related recall.

No additional predicate devices were used in this submission.

IV. DEVICE DESCRIPTION

The LENSAR Laser System - fs 3D (LLS-fs 3D) is a medical device for use in ophthalmic surgery. The device utilizes a pulsed laser that can be used to cut a precision capsulotomy in the anterior lens capsule, to fragment the cataractous lens for removal during cataract surgery, and to create full and partial thickness single-plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure. Use of the laser provides automated precision control of the size of the capsular opening; the type and parameters of laser phaco fragmentation treatment within the lens; as well as the size, architecture of incisions within the cornea, and depth of arcuate incisions.

The LLS-fs 3D is a laser system designed for non-invasive treatment of the crystalline lens by photo-disruptive laser cutting of the lens tissue. The LLS-fs 3D may replace the conventional manual capsulorrhexis procedure with an automated, laser assisted capsulotomy procedure and laser phaco fragmentation.

A key function in the LLS-fs 3D is the Augmented Reality™ Imaging System, which uses precise biometric data collected at multiple angles and optical ray-tracing technology to form a 3-D model of each individual patient's eye. Accurate biometric measurements are required to ensure accurate placement of the femtosecond laser pulses used for various surgical procedures. The Augmented Reality™ Imaging System uses enhanced depth of field of ocular structures and super luminescent diode (SLD) illumination to generate an in-focus image from the anterior cornea to the posterior lens capsule. The SLD is a continuous wave (cw) device with a beam emitting from the same aperture as the treatment laser. Variable-rate scanning ensures optical contrast to capture all ocular structures within the anterior segment of the eye. Using the biometric data collected, the LLS-fs 3D has the ability to detect even the smallest amount of lens tilt from the optical axis.

The LLS-fs 3D operates in the following manner: After dilation of the pupil, the laser is "docked" to the eye, and the eye is then optically scanned to determine the location, size, and shape of the crystalline lens and the cornea. The treatment parameters are entered by the user, and with the information from the scan, the control system computes a custom treatment pattern of photodisruptive laser pulses tailored to the individual eye.

The associated accessories that are packaged separately, but may be shipped as part of the LLS-fs 3D system include:

- LENSAR Laser System Accessory Kit
- Patient Interface Device (PID) Kit (consisting of a Suction Ring and a Window Assembly)
- Patient Interface Device (PID) Ring Arm Kit
- Optical Calibration Fixture
- Calibration Windows

V. INDICATIONS FOR USE

The LENSAR Laser System - fs 3D (LLS-fs 3D) is intended for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, laser phacofragmentation, and the creation of full and partial thickness single-plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

The indication for use of the subject device is unchanged from that of the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The LLS-fs 3D femtosecond laser system, including pulse energy control and monitoring, used in the subject LLS-fs 3D is the same as that used in the predicate device cleared in K123859. The primary difference between the subject LENSAR Laser System – fs 3D device and the predicate device is the addition of key features to enhance the surgeon's

ease of use. The subject and predicate devices are both based on the following technological elements:

- a pulsed laser used to generate incisions in the patient's crystalline lens, lens capsule and/or cornea by contiguous placement of a series of laser pulses
- an optical beam delivery system to accurately deliver the laser pulses to the correct locations within the patient's crystalline lens and cornea
- a moveable optical head to allow the laser to be moved into position to dock to the patient interface device from either the temporal or superior direction for either eye as required by the physician and procedure room set-up
- a corneal contact-free patient interface device and controlled force docking mechanism that positions and mechanically stabilizes the patient's eye during all laser surgical procedures
- a biometric system to measure the position and shape of the crystalline lens and cornea so that the photodisruption pattern can be accurately placed
- a camera system to provide the user with a view of the eye during the eye "docking" operation and periodic snapshots of the eye to allow the user to monitor the laser treatment
- a software control system which controls the laser, beam delivery, and patient positioning as well as storing treatment information
- an intuitive user interface (two Technician Monitors, a Surgeon Monitor, and a single Joystick) to permit the user to manage all aspects of the system

The following technological differences exist between the subject and predicate devices:

- A minor modification to the Patient Interface Device, for both ergonomics and improving ease of use.
- The provision of features incorporated into the laser system to enhance ease of use for the surgeon. All are used to provide the surgical guidance and documentation of treatments to aid the surgeon during anterior segment ophthalmic surgical procedures. All can be selected or adjusted by the surgeon at his/her discretion during the procedure.
    - The Eye Viewing System includes a software function added for Iris Registration to address cyclorotation.
    - Cataract density imaging menu (CustomFrag) available for ease of selection of fragmentation patterns permitted by the cleared LLS-fs 3D.
    - Wireless communication system to support Remote Diagnostic use by Technical Service staff, on-line purchase of procedure certificates, import of preoperative diagnostic data from other diagnostic devices in the surgical suite, and export of treatment data to a printer, or the LENSAR Server.
- The Biometric System includes an addition of temperature stabilization hardware and software modifications.
- The Energy Monitor portion of the Beam Delivery system has been enhanced with a temperature stabilized photo detector.
- The Controlled Force Docking System and Moveable Optical Head hardware includes firmware and software changes to improve user docking experience.
- Software changes were made to the Beam Delivery and Placement System to permit a multi-chop pattern.

- The Graphical User Interface (GUI) has evolved to support new features and improve ergonomics.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing:
Biocompatibility evaluations of materials coming in contact with the patient or patient fluid path in the LENSAR Laser System – fs 3D (LLS-fs 3D) were conducted in accordance with the following standards.

Standard Number	Title
ANSI/AAMI/ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, 3 ed.
ANSI/AAMI/ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for cytotoxicity, *in vitro* methods, 2 ed.
ANSI/AAMI/ISO 10993-10:2002; A1:2006	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity, 2 ed.

PID Kit:
The PID Kit is single-use and is sterilized via gamma radiation. The following testing was done:

- Cytotoxicity
- Irritation
- Sensitization
- Chemical Testing
- Physical Testing

The method of validation followed AAMI TIR27 – VDMax. This was used to ensure a sterility assurance level of 10^{-6}. The packaging is made of a pre-formed plastic with a peel-pouch top surface. The material is Tyvek 1059B which is gamma sterilization compatible. A Cobalt-60 gamma radiation dose was used to ensure the PID Kit is sterile.

PID Interface Arm:
The PID Interface Arm is multi-use and is sterilized by autoclaving. The Cleaning Validation was performed in accordance with the AAMI TIR30:2011 guidance document. All test method acceptance criteria were met per the specified criteria.

Electrical Safety and Electromagnetic Compatibility (EMC):
Electromagnetic compatibility and electrical safety was evaluated for the LLS-fs 3D. The addition of new features and updated software necessitated a current evaluation to that of the established EMC testing provided in K123859. The system underwent testing to:

- UL 60601-1 2nd Edition Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- EN 60601-1 2nd Edition Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- EN 60601-1-2 3rd Edition Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-2007 Medical Electrical Equipment – Collateral Standard: Electromagnetic Compatibility Requirements.

Testing showed that the system met or exceeded the requirements. Electromagnetic compatibility and electrical safety was performed by a Nationally Recognized Test Laboratory (NRTL).

Eye Safety Analysis:
The addition of features to the laser system is accompanied by an upgraded Super Luminescent Diode (SLD) for use with the Scheimpflug camera. The LENSAR Laser System Super Luminescent Diode (SLD) was determined to be safe using the methods described in ISO 15004-2:2007, Ophthalmic Instruments.

Software Verification and Validation Testing:
A complete software verification and validation testing was conducted covering all cited changes and updates since the prior clearance (K123859), and documentation was provided as recommended by FDA's *Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury to the patient or operator.

Performance Evaluation of the Iris Registration Feature:
Verification and validation testing were completed to demonstrate that the device performance complies with specifications and requirements identified for the LENSAR Iris Registration feature. All criteria were met and the results demonstrate that LENSAR Iris Registration feature meets all performance specifications and requirements.

Performance Evaluation of the Cataract Density Imaging Feature:
Verification and validation testing were completed to demonstrate that the device performance complies with specifications and requirements identified for the LENSAR cataract density imaging feature. All criteria were met and the results demonstrate that LENSAR cataract density imaging feature meets all performance specifications and requirements.

Animal Study:
Ex vivo animal studies completed for this submission involved verification in porcine eyes of the Beam Delivery and Placement requirements for the upgrade to software. Evaluations involved confirmation of capsule clearance (anterior and posterior), corneal

incisions for fixed or proportional depth for arcuate incisions, and the selected proportional depth of the clear corneal incisions.

In addition, the performance of the laser in meeting requirements for the safety feature (Residual Stroma Override) was demonstrated. The Residual Stroma Override feature overrides the fixed depth selection, to ensure that a user specified minimum residual stromal bed is maintained if an incision of greater fixed depth is requested by the User.

The animal studies conducted were performed in compliance with the applicable requirements of Good Laboratory Practices (GLP) regulation 21 CFR Part 58.

Clinical Studies:
These additional features and software updates do not change the Indication for Use. Thus no clinical evaluations are required as part of this submission.

VIII. CONCLUSIONS

Based on the above supportive documentation, the LLS-fs 3D with the addition of features for iris registration for placement of corneal incisions and for cataract density imaging to select fragmentation patterns (CustomFrag), with the updated software validations, is substantially equivalent with respect to technological characteristics and Indication for Use to the LENSAR Laser System – fs 3D (K123859).